Hearing Date and Time: March 23, 2022, at 10:00 a.m. (prevailing Eastern Time)
Objection Date and Time: March 16, 2020, at 4:00 p.m. (prevailing Eastern Time)

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
Eli J. Vonnegut
Christopher S. Robertson

Counsel to the Debtors
and Debtors in Possession

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF HEARING REGARDING MOTION OF DEBTORS FOR AUTHORIZATION TO ENTER INTO AMENDED AND RESTATED FUNDING AGREEMENT

PLEASE TAKE NOTICE that on March 2, 2022, the above-captioned debtors and debtors in possession (collectively, the "**Debtors**") filed the *Amended Motion of Debtors for Authorization to Enter into Amended and Restated Funding Agreement* (the "**Motion**"). A hearing

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

on the Motion will be held on **March 23, 2022, at 10:00 a.m. (prevailing Eastern Time)** (the "**Hearing**") before the Honorable Judge Robert D. Drain, United States Bankruptcy Judge, United States Bankruptcy Court for the Southern District of New York, 300 Quarropas Street, White Plains, New York 10601 (the "**Bankruptcy Court**"), or at such other time as the Bankruptcy Court may determine.

PLEASE TAKE FURTHER NOTICE that pursuant to General Order M-543, dated March 20, 2020 (Morris, C.J.) ("**General Order M-543**"), the Hearing shall be conducted **via Zoom for Government®** so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.[2]

PLEASE TAKE FURTHER NOTICE that the Hearing may be continued or adjourned thereafter from time to time without further notice other than an announcement of the adjourned date or dates at the Hearing or a later hearing. The Debtors will file an agenda before the Hearing, which may modify or supplement the motions to be heard at the Hearing.

PLEASE TAKE FURTHER NOTICE that any responses or objections (the "**Objections**") to the Motion shall be in writing, shall conform to the Federal Rules of Bankruptcy Procedure and the Local Bankruptcy Rules for the Southern District of New York, shall be filed with the Bankruptcy Court (a) by attorneys practicing in the Bankruptcy Court, including attorneys admitted *pro hac vice*, electronically in accordance with General Order M-399 (which can be found at www.nysb.uscourts.gov), and (b) by all other parties in interest, on a CD-ROM, in text-searchable portable document format (PDF) (with a hard copy delivered directly to Chambers), in accordance with the customary practices of the Bankruptcy Court and General Order M-399, to

[2] A copy of General Order M-543 can be obtained by visiting http://www.nysb.uscourts.gov/news/court-operations-under-exigent-circumstances-created-covid-19.

the extent applicable, and shall be served in accordance with the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on November 18, 2019 [ECF No. 498], so as to be filed and received no later than **March 16, 2022** at **4:00 p.m.** (prevailing Eastern Time) (the "**Objection Deadline**").

PLEASE TAKE FURTHER NOTICE that if no Objections are timely filed and served with respect to the Motion, the Debtors may, on or after the Objection Deadline, submit to the Bankruptcy Court an order substantially in the form of the proposed order annexed to the Motion, which order may be entered without further notice or opportunity to be heard.

PLEASE TAKE FURTHER NOTICE that objecting parties are required to attend the Hearing, and failure to appear may result in relief being granted upon default; *provided* that objecting parties shall attend the Hearing via Zoom for Government so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.

PLEASE TAKE FURTHER NOTICE that copies of the Motion may be obtained free of charge by visiting the website of Prime Clerk LLC at https://restructuring.primeclerk.com/purduepharma. You may also obtain copies of any pleadings by visiting the Bankruptcy Court's website at http://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

Dated: March 2, 2022
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
Eli J. Vonnegut
Christopher S. Robertson

Counsel to the Debtors
and Debtors in Possession

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[3]	**(Jointly Administered)**

MOTION OF DEBTORS FOR AUTHORIZATION
TO ENTER INTO AMENDED AND RESTATED FUNDING AGREEMENT

[3] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

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Purdue Pharma L.P. ("**PPLP**") and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") respectfully state as follows:

Relief Requested

1. By this Motion (the "**Motion**"), and pursuant to sections 105(a) and 363(b) of the United States Code, 11 U.S.C. § 101, *et seq*. (as amended or modified, the "**Bankruptcy Code**"), the Debtors seek entry of an order, substantially in the form attached hereto as **Exhibit A** (the "**Order**"), authorizing the Debtors to enter into and perform under an amended and restated funding agreement (the "**A&R Agreement**") by and between PPLP and Harm Reduction Therapeutics, Inc. ("**HRT**"), substantially in the form attached hereto as **Exhibit B**, which A&R Agreement amends and restates that certain Funding Agreement (the "**2020 HRT Agreement**"), dated as of June 25, 2020, by and between PPLP and HRT.

Jurisdiction and Venue

2. The United States Bankruptcy Court for the Southern District of New York (the "**Court**") has jurisdiction to consider this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.). This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2) and, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedure (the "**Bankruptcy Rules**"), the Debtors consent to entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter a final order or judgment consistent with Article III of the United States Constitution.

3. Venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409.

General Background

4. On September 15, 2019 (the "**Petition Date**"), the Debtors each commenced with this Court a voluntary case (collectively, the "**Cases**") under chapter 11 of the Bankruptcy Code. The Debtors are authorized to operate their businesses and manage their properties as debtors in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. On September 27, 2019, the United States Trustee for the Southern District of New York appointed the official committee of unsecured creditors (the "**Creditors' Committee**"). No trustee has been appointed in these Cases.

5. On June 25, 2020, the Court entered an order [ECF No. 1301] (the "**2020 HRT Order**") granting the *Amended Motion of Debtors for Authorization to Enter into Funding Agreement* [ECF No. 1249] (the "**2020 HRT Motion**") and authorizing the Debtors' entry into and performance under the 2020 HRT Agreement.

6. Additional information about the Debtors' businesses and the events leading up to the Petition Date can be found in the *Debtors' Informational Brief* filed on September 16, 2019 [ECF No. 17].

Preliminary Statement

7. Naloxone is an opioid antagonist "rescue drug" that can counter the effects of an opioid overdose. In June of 2020, this Court approved the Debtors' request to provide up to $6.5 million of funding to HRT, a non-profit pharmaceutical company founded in 2017 whose mission is to prevent opioid overdose deaths by making a low-cost naloxone nasal spray device available over the counter ("**OTC**").[4] With this support, and as discussed in greater detail below, HRT recently completed a successful clinical trial that will allow it to proceed with filing a New Drug

[4] 2020 HRT Order.

Application (the "**NDA**"), currently expected in the fall of 2022, and advance its packaging, labeling, and commercial manufacturing work. Barring delays (including delays in funding) HRT anticipates (but cannot guarantee) that FDA may approve its product (brand name RiVive™) in mid-2023 with commercial availability anticipated in early 2024.[5]

8. Low-cost, OTC naloxone is needed now more than ever. According to the Centers for Disease Control and Prevention, there were over 75,000 deaths from opioid overdoses in the 12-month period ending in April 2021, up from approximately 56,000 the year before.[6] Thousands of overdose deaths could be prevented if individuals, families, first responders and communities had greater access to naloxone.[7] However, two substantial barriers to access to this potentially life-saving medication—price and the need for a prescription—stand in the way. The cost of intranasal naloxone remains high. A single twin-pack of brand-name Narcan® retails for about $125.[8] A second branded naloxone nasal spray product, Kloxxado™, was approved by the FDA in April 2021,[9] and generic versions of Narcan were launched in December of 2021.[10] The

[5] Timing of FDA approval subject to FDA process and discretion.

[6] Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 Annually, https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.

[7] *See* Centers for Disease Control and Prevention, *Featured Topics: Save Lives Now*, https://www.cdc.gov/drugoverdose/featured-topics/save-lives-now.html.

[8] *See, e.g.*, Drugs.com, Narcan Nasal Spray Prices, Coupons and Patient Assistance Programs, https://www.drugs.com/price-guide/narcan-nasal-spray.

[9] U.S. Food and Drug Admin., FDA News Release, *FDA Approves Higher Dosage of Naloxone Nasal Spray to Treat Opioid Overdose* (April 30, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose.

[10] Teva Pharmaceutical Industries Limited, Teva Announces Launch of First-to-Market Generic Version of Narcan® (Naloxone Hydrochloride Nasal Spray), in the U.S. (December 22, 2021), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-launch-of-first-to-market-generic-version-of-narcan-naloxone-hydrochloride-nasal-spray/; Sandoz, Sandoz launches authorized generic of Narcan® (naloxone hydrochloride) Nasal Spray 4 mg in US to help reverse opioid overdose, expanding access during surge in overdose deaths (December 22, 2021), https://www.us.sandoz.com/news/media-releases/sandoz-launches-authorized-generic-narcan-naloxone-hydrochloride-nasal-spray-

introduction of these products has not translated to a material reduction in price, as the generic formulations remain at approximately 85% the price of Narcan and Kloxxado. In other words, even generic intranasal naloxone costs over $100 a twin-pack.[11] And all of these products are prescription only. Indeed, Debtors are aware of no other OTC naloxone product that is advanced in its development as HRT's.

9. Concerned that patients and consumers are often unable or unwilling to go through the process of visiting a doctor and navigating their insurance coverage in order to obtain a prescription for naloxone that they then must have filled by a pharmacist, states have enacted legislation or issuing standing orders enabling the sale of naloxone without a prescription.[12] These measures, however, do not adequately clear the barriers to access, as they require individuals to request (sometimes at some embarrassment) the medication from a pharmacist from "behind the counter."[13] In addition, standing orders cannot be used by harm reduction groups to purchase bulk supplies of naloxone.[14] Due to the relative high cost and other impediments to obtaining prescription naloxone, barriers to access persist.[15]

4#:~:text=Princeton%2C%20New%20Jersey%2C%20December%2022%2C%202021%20%E2%80%94%20Sandoz%2C,US%20via%20retail%20pharmacies%20and%20institutions%2C%20including%20hospitals.

[11] *See, e.g.*, Drugs.com, Narcan Nasal Spray Prices, Coupons and Patient Assistance Programs, https://www.drugs.com/price-guide/narcan-nasal-spray.

[12] SAFEProject, State Naloxone Access Rules and Resources, https://www.safeproject.us/naloxone-awareness-project/state-rules/.

[13] Murphy, S. et al., *Will Converting Naloxone to Over-the-Counter Status Increase Pharmacy Sales?* Health Services Research, 2019; Vol. 54, No. 4, pp. 764–772, 771 ("[M]oving naloxone to OTC would help normalize the purchasing process, and likely reduce concerns of stigma by customers, which would also serve to increase demand.").

[14] *See, e.g.*, Pattani, Aneri, *To Save Lives, Overdose Antidote Should Be Sold Over-the-Counter, Advocates Argue*, NPR (Dec. 14, 2021).

[15] *See id.* ("The cost of the medication, requirements to show ID, a fear of discrimination from pharmacists and an inability to find a pharmacy that stocks naloxone are all barriers."); Murphy et al., *supra* note 13, at 54:764–772

10. The Food and Drug Administration agrees that greater availability of naloxone would be an important public health advancement, and has been actively encouraging drug companies to increase access to naloxone by developing an OTC product.[16] Notably, in January of 2019, the FDA announced that it had developed a model Drug Facts label, which is required for OTC drug products, for both a nasal spray and an autoinjector device, and that the FDA had itself conducted the comprehensive testing that drug companies normally must complete to demonstrate that the instructions on the label are simple to follow.[17] This marks the first time that the FDA has ever proactively developed and tested a Drug Facts label for a drug to support development of an OTC product. The FDA stated that it took this extraordinary step because some potential entrants identified the label design and testing process as a barrier to development.[18]

11. The American Medical Association likewise strongly supports improved access to naloxone. Most recently, on February 15, 2022, the AMA published a letter to the U.S. Surgeon General urging "removing the prescription status of naloxone as an essential step to save lives

(making an OTC naloxone product available could result in a "substantial increase" in naloxone pharmacy sales, potentially as high as 179%).

[16] *See, e.g.*, U.S. Food and Drug Admin., FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's efforts to advance new ways to increase the availability of naloxone as one means for reducing opioid overdose deaths* (Oct. 23, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-efforts-advance-new-ways-increase-availability; U.S. Food and Drug Admin., FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths* (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over; U.S. Food and Drug Admin., FDA Statement, *Statement on continued efforts to increase availability of all forms of naloxone to help reduce opioid overdose deaths* (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.

[17] U.S. Food and Drug Admin., FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths* (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over.

[18] *Id*.

from opioid-related overdose because it will help make naloxone more readily available to patients everywhere."[19] This statement is the latest in a series of pleas from the AMA for the approval of OTC naloxone.[20] In addition, numerous media sources have reported on the need for improved access to naloxone.[21] Nevertheless, Debtors are aware of no other organization as advanced as HRT in responding to the FDA's call for an OTC naloxone nasal spray device.

12. The Debtors' near-term financial support is absolutely critical to these efforts. The Debtors are seeking authority at this time to provide up to $11 million of additional funds to HRT over the course of 2022. The initial $3 million would be funded upon approval of the A&R Agreement,[22] with subsequent amounts in or around September and November 2022, subject to HRT achieving certain developmental milestones.

13. Support for the development of OTC naloxone is one of three key initiatives (the "**Public Health Initiatives**") that the Debtors are pursuing as part of their commitment to advance

[19] Madara, J.L., Am. Med. Ass'n, *Letter to the Honorable Rahul Gupta, MD, Director, White House Office of National Drug Control Policy* (Feb. 15, 2022), https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-2-15-Letter-to-Gupta-re-ONDCP-Naloxone.pdf.

[20] *E.g.*, Madara, J.L., Am. Med. Ass'n, *Letter to Emergent BioSolutions* (Nov. 4, 2021), https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-11-4-Emergent-BioSolutions-FINAL.pdf; Am. Med. Ass'n, AMA Statement, *AMA: FDA action on OTC naloxone will save people from overdoses* (Jan. 17, 2019), https://www.ama-assn.org/press-center/ama-statements/ama-fda-action-otc-naloxone-will-save-people-overdoses ("As called for by AMA policy and ongoing advocacy, today's action should spur efforts by naloxone manufacturers to submit applications for their products to receive over-the-counter status. Doing so would be an important step to save even more lives from a national epidemic.").

[21] *E.g.*, Pattani, Aneri, *To Save Lives, Overdose Antidote Should Be Sold Over-the-Counter, Advocates Argue*, NPR (Dec. 14, 2021); Lee, Jacquie, *Naloxone Dispensing Is Way Up, but Some Areas Still Lag Behind*, BLOOMBERG LAW (Nov. 26, 2019); Gerencher, Kristen, *FDA Urges Broader Access to Naloxone to Avoid Opioid Overdose Deaths*, FORBES (Sept. 25, 2019); Court, Emma, *130 Americans Die Each Day from Opioid Overdoses. Experts Are Asking Why a Lifesaving Treatment Isn't Widely Available Without a Prescription*, BUSINESS INSIDER (Sept. 23, 2019).

[22] The 2020 HRT Agreement contemplated a $5 million "Third Milestone Payment" upon completion of the "Phase 1 Study's Clinical Study Report," which Third Milestone Payment was subject to approval by further order of the Court. The first $3 million milestone payment set forth in the A&R Agreement supersedes the Third Milestone Payment in the 2020 HRT Agreement.

meaningful solutions to the opioid crisis and as set forth in their plan of reorganization.[23] The *Twelfth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors* [ECF No. 3726] (the "**Plan**") and the agreements embodied therein contemplate that the Debtors' businesses will be transferred to a new entity, Knoa Pharma, that will be indirectly owned by abatement trusts established for the benefit of state, municipal and tribal creditors and operated in the public interest. The precise proposed terms of Knoa Pharma's ownership and governance structure are the product of extensive negotiations among the Debtors, the ad hoc committee of governmental and other contingent litigation claimants (the "**AHC**"), the Creditors' Committee, the Department of Justice and other stakeholders, including within the context of the second phase of mediation in these cases.[24] Among other negotiated terms, Knoa Pharma would continue to support the development and efficacy of the Public Health Initiatives, subject to an agreed budgeted amount (the "**PHI Budget**") of $50 million *minus* the Debtors' expenditures on Public Health Initiatives on and after June 30, 2021.[25] The Debtors submit that Court approval of additional, critically needed funding for HRT is entirely consistent with this highly-negotiated Public Health Initiative funding and support framework.

HRT Recently Achieved Success in a Key Clinical Study

14. New drug development is a complex process, and the path to FDA approval often entails setbacks and delays. RiVive's FDA approval process was delayed in the spring of 2021,

[23] The other two principal initiatives are the development of emergency opioid overdose treatments containing the opioid antagonist nalmefene and the development and distribution of a generic version of Suboxone® tablets, a leading opioid addiction treatment consisting of a combination of buprenorphine and naloxone Debtors obtained FDA approval for a vial form of nalmefene on February 8, 2022, and approval for their generic Suboxone in 2020.

[24] *Disclosure Statement for Fifth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors* [ECF No. 2983] (the "**Disclosure Statement**") Art. III.U.

[25] *See Thirteenth Plan Supplement Pursuant to Sixth Amended Plan, Exhibit W, NewCo Operating Agreement* [ECF No. 3528].

when HRT's initial clinical study, which compared a key indicator of drug absorption of HRT's intranasal naloxone formulation to a reference intramuscular naloxone injectable dose, did not meet its primary endpoint. Upon receiving the results, HRT identified potential issues with the administration procedures and protocols and developed a redesigned study to demonstrate that RiVive is comparable to the FDA-approved comparator, which was a 0.4 mg intramuscular dose that has repeatedly been shown to reverse the vast majority of real-world overdoses.

15. The redesigned study, which was completed in January 2022, was a success. With this key hurdle now cleared, HRT is preparing to file the NDA for RiVive and is advancing its packaging, labeling, and manufacturing work to prepare for commercialization. Barring delays (including delays in funding) HRT anticipates (but cannot guarantee) that FDA may approve RiVive in mid-2023 with commercial availability likely following in early 2024.[26]

HRT Is Well Positioned to Bring OTC Naloxone to Market

16. HRT's management team has a long and successful history transitioning prescription medications to OTC. Members of the management team have helped develop OTC versions of products such as Nicorette®, Plan B®, Nasacort® Allergy, NicoDerm® CQ®, Prilosec OTC® and Allegra®, among others. Members of the team also have deep expertise in addiction research and substance abuse treatment.

17. HRT possesses a proprietary preservative-free 3 mg naloxone formulation that is well suited to intranasal delivery. To date, with the Debtors' financial and technical support, HRT has developed its intranasal naloxone formulation, received preliminary FDA approval for the RiVive trade name, established scientific and advisory boards, identified key vendors, including a contract manufacturer and a sales and distribution vendor, successfully completed the clinical

[26] Timing of FDA approval subject to FDA process and discretion.

study described above and has begun to prepare the NDA. The device that will deliver RiVive is field-tested, with over 25 years of FDA approvals for administration of, among other medicines, Narcan, migraine medications, anti-epilepsy medications and vitamin B12 applications.

HRT Requires Additional Near-Term Funding

18. Under the 2020 HRT Agreement, the Debtors provided $4 million of funding upon commencement of the first clinical study. The 2020 HRT Agreement provided for an additional $5 million milestone payment, subject to further Court approval, upon completion of that study's Clinical Study Report, which is a report indicating that certain data that is critical to filing an NDA has been collected. As discussed above, because the first study did not meet its primary endpoint, HRT did not satisfy this milestone until January of 2022.

19. HRT has therefore not received any funding from the Debtors since September of 2020, nor has it been able to obtain capital from other sources. By reducing expenses to an absolute minimum, including by suspending salaries and halting work on preparing to submit the NDA, HRT was nevertheless able to fund the redesign and conduct of a successful clinical study using remaining cash on hand. However, as HRT resumes work on preparing to submit the NDA and commercialize RiVive, the need for additional funding is acute. As it continues the necessary work to progress the development of RiVive, HRT anticipates that without additional financial support it will be out of cash by the end of April.

20. Further delay of the development timeline could substantially delay the approval and launch of this potentially life-saving medication. For instance, the Debtors understand that if HRT were to stop work on the 24-month drug stability program the entire program would have to be restarted from the beginning, likely resulting in a 2-3 year delay before HRT could file an NDA with the FDA.

21. To provide this necessary funding, the A&R Agreement provides for three Milestone Payments in an aggregate amount of $11 million, with each payment subject to HRT meeting certain Milestone Events. The Milestone Events and associated Milestone Payments are:

Milestone Event and Primary Purpose	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Clinical study successfully demonstrates that RiVive naloxone concentrations are as high as the FDA approved comparator product (Development, drug product stability, NDA preparation, device reliability and production equipment)	$3,000,000	Completion date: January 31, 2022. Milestone achieved. Payment Due Date: April 1, 2022
Acceptable drug product 24-month stability achieved to support targeted 24-month shelf life for commercial product (NDA preparation, pre-validation batch manufacture, sales & marketing preparations and on-going development work)	$3,000,000	Targeted completion date: August 31, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met
New Drug Application for RiVive filed with the FDA (Manufacturing site readiness, partial support of commercial batch components, sales and marketing support prior to 1st commercial shipment)	$5,000,000	Targeted completion date: October 28th, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met

22. The timing and amount of the Milestone Payments are structured such that the amount of each Milestone Payment is sufficient only to bridge HRT to the next Milestone Event. HRT does not maintain excess cash or a line of credit that could provide a cushion in the event that the Debtors do not or cannot make an anticipated Milestone Payment.

23. As described above, to the extent that HRT satisfies a Milestone Event and the Debtors make a Milestone Payment under the A&R Agreement, such Milestone Payment would be applied against the PHI Budget, which was highly negotiated among the Debtors, the AHC, the Creditors' Committee, the DOJ, and other key creditor constituencies.

If the Motion Is Denied, HRT Is Unlikely to Secure Timely Alternative Financing

24. The Debtors remain the only source of funding for HRT to date. The 2020 HRT Agreement required HRT to "use commercially reasonable efforts taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties for the development of the Product and to supply funding for supply readiness and launch of the Product."[27] The Debtors understand that HRT recently approached two private companies in the opioid use disorder/mental health therapy space and four major philanthropic organizations. However, despite these efforts, the Debtors understand that no alternative funding was available.

25. At least five factors help explain HRT's lack of additional outside funding sources to date despite the many voices supporting its life-saving mission. First, drug development is expensive, and only the largest philanthropies have the capacity to contribute millions of dollars of capital. There are no large non-profit or charitable organizations (e.g., the American Cancer Society, which gathers donations for cancer research and therapies) dedicated to supporting the development of rescue drugs. Second, most philanthropic organizations are more accustomed to funding drug distribution (e.g., anti-malarial medicines) but not to the regulatory and scientific complexity inherent in the highly technical process of drug development. The lack of pharmaceutical development subject matter expertise within philanthropic organizations makes it particularly difficult for these organizations to evaluate potential contributions to HRT. Third, there is very little precedent for nonprofit pharmaceutical companies. To the Debtors' knowledge there are currently only two other nonprofit pharmaceutical companies with demonstrable drug development experience, Medicines360, which is focused exclusively on women's health, and

[27] 2020 HRT Agreement ¶ 4.2(E).

CivicaRx, a nonprofit producing drugs to address the in-hospital drug shortage crisis, neither of which is involved with developing overdose reversal products. The lack of precedent adds a further element of uncertainty to any decision by a philanthropic organization to provide financial support to HRT. Fourth, many of the largest philanthropic organizations (e.g., the Bill and Melinda Gates Foundation) have a global focus, rendering U.S.-centric efforts less attractive to them. Finally, there are limited opportunities for direct support from state or federal agencies. In addition, HRT's corporate model makes the company unattractive to debt financing, as HRT does not expect to generate excess funds to service interest expense or repay principal.

26. The Debtors appreciate the importance of OTC naloxone from a public health perspective and are uniquely positioned to provide financial support to HRT. As a pharmaceutical company with sophistication in drug development, the Debtors understand the regulatory and scientific complexity associated with HRT's mission and appreciate the value of HRT's unparalleled experience transitioning prescription medications to OTC. The Debtors have the financial wherewithal to make a multi-million dollar contribution and are not limited by competing charitable demands or geographic scope in the same way that philanthropic organizations may be. Moreover, there is no expectation that a contribution to HRT would ever be paid back, which makes it unlikely that other for-profit pharmaceutical companies will be interested in lending their support.

27. The A&R Agreement continues to require that HRT seek alternative funding. It is possible that HRT may be more attractive to other third-party sources of capital now that it has conducted the successful clinical study.

The Relief Requested Is Limited in Scope

28. As discussed above, if this Motion is granted, the Debtors will be obligated to fund—in three installments and subject to milestones—a maximum of $11 million under the A&R Agreement, all of which would count against the PHI Budget and which would enable HRT to submit the NDA for RiVive and advance packaging, labeling, and manufacturing work to prepare for commercialization. The Debtors will not be obligated to conduct any future commercialization activities or purchase any product. The milestones contained in the A&R Agreement provide appropriate checks on the Debtors' funding requirements if HRT encounters any future setbacks or delays. The Debtors are free to assign their commitment to any other party. Finally, certain creditor protections and accommodations that were present in the 2020 HRT Agreement, including that HRT will return Purdue's prior contributions and that Purdue will be entitled to 40% of HRT's equity interests (an increase from 20% in the 2020 HRT Agreement) if HRT later becomes a for-profit entity, remain in the A&R Agreement.

Basis for Relief Requested

29. Bankruptcy Code section 363(b)(1) empowers the Court to authorize a debtor to "use, sell, or lease, other than in the ordinary course of business, property of the estate." To approve the use of estate property under section 363(b)(1) of the Bankruptcy Code, the Second Circuit requires a debtor to show that the decision to use the property outside of the ordinary course of business was based on the debtor's sound business judgment in light of "all salient factors" relating to the bankruptcy case. *Comm. of Equity Sec. Holders v. Lionel Corp. (In re Lionel Corp.)*, 722 F.2d 1063, 1070-71 (2d Cir. 1983) ("The rule we adopt requires that a judge determining a § 363(b) application expressly find from the evidence presented before him at the hearing a good business reason to grant such an application."); *In re Ionosphere Clubs, Inc.*, 100 B.R. 670, 675

(Bankr. S.D.N.Y. 1989); *see also In re MF Global Inc.*, 467 B.R. 726, 730 (Bankr. S.D.N.Y. 2012) ("Although not specified by section 363, the Second Circuit requires that transactions under section 363 be based on the sound business judgment of the debtor or trustee.").

30. Section 105(a) of the Bankruptcy Code provides that the "court may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a). Pursuant to section 105(a), orders are appropriate where they are essential to the debtor's reorganization efforts and do not pose a burden on the debtor's creditors. *See U.S. Lines, Inc. v. Am. S.S. Owners Mut. Prof. & Indem. Ass'n (In re U.S. Lines, Inc.)*, 197 F.3d 631, 640 (2d Cir. 1999); *Momentum Mfg. Corp. v. Emp. Creditors Comm. (In re Momentum Mfg. Corp.)*, 25 F.3d 1132, 1136 (2d Cir. 1994) ("It is well settled that bankruptcy courts are courts of equity, empowered to invoke equitable principles to achieve fairness and justice in the reorganization process.").

31. Under the unusual circumstances of these Cases, the "salient factors" considered when evaluating the Debtors' business judgment, and whether the Debtors' decision to fund HRT's efforts would aid the Debtors' reorganization, must include how funding HRT would benefit all of the Debtors' contingent creditors and the American public at large. The Court has previously observed that "the Debtors' cases are highly unusual" in that "the Debtors are largely in a [sui generis] position whereby they have already agreed to turn over all of their value to their creditors," Hr'g Tr. 159:16-19 (Nov. 19, 2019), and that "this is a fundamentally public health crisis driven case where the claimants, in one sense, can be almost every citizen in the country." Id. at 159:9-12. As a result, the Court concluded that it should consider "how the public at large is to benefit" from a request by the Debtors to use property outside of the ordinary course of business. Id. at 160:17-20.

32. The Debtors' decision to fund HRT's development of OTC naloxone is a sound exercise of the Debtor's business judgment and will hopefully facilitate and progress an initiative that could save thousands of lives. As discussed above, development of an OTC naloxone product is strongly encouraged by the FDA and the American Medical Association and broadly supported by academic studies. Moreover, only one company—HRT—is presently working towards bringing this potentially life-saving product to market.

33. Since September of 2018, the Debtors have continued to provide modest but vital financial support to HRT in an effort to advance meaningful solutions to the opioid crisis. Purdue made its initial decision to fund HRT, and its later decisions to provide additional funding, after careful evaluation of, among other things, the critical need for OTC naloxone, the close fit between HRT's and Purdue's PHI goals, detailed supporting budgets and development timelines, Purdue's own financial position, and HRT's capabilities and prospects of success. Before making each additional contribution to HRT, Purdue carefully evaluated HRT's progress toward bringing OTC naloxone to market, and how Purdue's contribution would allow HRT to achieve concrete milestones on the path to that goal. The Debtors' sophistication in pharmaceutical development also informed their assessment of HRT's funding proposals and the structure of the resulting funding agreements.

34. Based on HRT's progress to date and need for additional funding, the Debtors now seek authority to provide up to $11 million of additional funding to HRT. The amount requested is based on a detailed budget and timeline, and the Debtors' obligation to make future milestone payments under the A&R Agreement is contingent on HRT achieving important developmental milestones.

Waiver of Stay Under Bankruptcy Rule 6004(h)

35. The Debtors also request that, to the extent applicable to the relief requested in this Motion, the Court waive the stay imposed by Bankruptcy Rule 6004(h), which provides that "[a]n order authorizing the use, sale, or lease of property other than cash collateral is stayed until the expiration of 14 days after entry of the order, unless the court orders otherwise." Fed. R. Bankr. P. 6004(h). As described above, the relief that the Debtors seek in this Motion is necessary for the Debtors to maximize the value of their estates. Accordingly, the Debtors respectfully request that the Court waive the 14-day stay imposed by Bankruptcy Rule 6004(h), as the nature of the relief sought herein justifies immediate relief.

Notice

36. Notice of this Motion will be provided as to (a) the entities on the Master Service List (as defined in the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on November 18, 2019 [ECF No. 498] and available on the Debtors' case website at https://restructuring.primeclerk.com/purduepharma) and (b) any person or entity with a particularized interest in the subject matter of this motion (the "**Notice Parties**"). The Debtors respectfully submit that no further notice is required.

No Prior Request

37. The Debtors have not previously sought the relief requested herein from the Court or any other court.

[Remainder of Page Intentionally Left Blank]

WHEREFORE, the Debtors respectfully request that the Court enter the proposed form of order, substantially in the form attached hereto, granting the relief requested herein and such other relief as the Court deems appropriate under the circumstances.

Dated: March 2, 2022
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Eli J. Vonnegut*

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
Eli J. Vonnegut
Christopher S. Robertson

Counsel to the Debtors
and Debtors in Possession

Exhibit A

Proposed Order

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: **PURDUE PHARMA L.P., *et al*.,** **Debtors.**[1]	**Chapter 11** **Case No. 19-23649 (RDD)** **(Jointly Administered)**

ORDER AUTHORIZING DEBTORS TO
ENTER INTO AMENDED AND RESTATED FUNDING AGREEMENT

Upon the motion (the "**Motion**")[2] of Purdue Pharma L.P. and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") for entry of an order, pursuant to sections 105(a) and 363 of the Bankruptcy Code, Bankruptcy Rules 6003 and 6004 and Rule 9013-1 of the Local Bankruptcy Rules for the Southern District of New York (the "**Local Rules**"), authorizing the Debtors to enter into an amended and restated funding agreement with Harm Reduction Therapeutics, Inc. ("**HRT**"), as more fully described in the Motion; and the Court having jurisdiction to consider the Motion and the relief requested therein pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b) and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.); and consideration of the Motion and the relief requested therein being a

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

[2] Unless otherwise defined herein, each capitalized term shall have the meaning ascribed to such term in the Motion.

core proceeding under 28 U.S.C. § 157(b); and venue being proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409; and due and proper notice of the Motion having been provided to the Notice Parties, and it appearing that no other or further notice need be provided; and the Court having reviewed the Motion and held a hearing to consider the relief requested in the Motion (the "**Hearing**"); and it appearing that the proposed funding agreement was negotiated and entered into at arms-length and in good faith; and, after due deliberation, the Court having determined that the legal and factual bases set forth in the Motion and at the Hearing establish good and sufficient cause for the relief granted herein, that entry into the funding agreement is a proper exercise of business judgment in the context of these cases, and that the relief requested is in the best interests of the Debtors and their estates; now, therefor;

IT IS HEREBY ORDERED THAT

1. The Motion is hereby granted as set forth herein.

2. Pursuant to sections 105(a) and 363(b) of the Bankruptcy Code, the Debtors are authorized to enter into and perform under the A&R Agreement, including to make the $3 million Milestone Payment in respect of the First Milestone Event, and subject to the satisfaction of the conditions for each, to make the $3 million Milestone Payment in respect of the Second Milestone Event, and the $5 million Milestone Payment in respect of the Third Milestone Event, in each case in accordance with the terms of the A&R Agreement.

3. Within 20 days of the end of each month, the Debtors shall provide each of the Committee and the Ad Hoc Committee with a copy of the monthly written report provided by HRT to PPLP pursuant to Section 2.5 of the A&R Agreement.

4. Any Bankruptcy Rule (including, but not limited to, Bankruptcy Rule 6004(h)) or Local Rule that might otherwise delay the effectiveness of this Order is hereby waived, and the terms and conditions of this Order shall be effective immediately and enforceable upon its entry.

5. The contents of the Motion and the notice procedures set forth therein are good and sufficient notice and satisfy the Bankruptcy Rules and the Local Rules, and no other or further notice of the Motion or the entry of this Order shall be required.

6. In the event that the Debtors seek future authorization to make additional payments to HRT not authorized under this Order, nothing herein shall limit or otherwise modify any party's right to object to the granting of such relief on any ground or the Court's evaluation of any such objection.

7. The Court shall retain jurisdiction to hear and determine all matters arising from or related to the implementation, interpretation and enforcement of this Order.

White Plains, New York
Dated: _____, 2022

THE HONORABLE ROBERT D. DRAIN
UNITED STATES BANKRUPTCY JUDGE

Exhibit B

Form of A&R Funding Agreement

A&P Draft 3/2/22

AMENDED AND RESTATED FUNDING AGREEMENT

This Amended and Restated Funding Agreement ("Agreement") is dated as of [•], 2022 between Harm Reduction Therapeutics, Inc., a nonstock Maryland not-for-profit corporation ("HRT"), and Purdue Pharma L.P., a Delaware limited partnership ("PPLP"). (As used herein, each of HRT and PPLP is referred to as a "Party" and collectively as the "Parties.")

WHEREAS, the Parties previously entered into a Funding Agreement, dated as of June 25, 2020 ("Funding Agreement");

WHEREAS, PPLP has provided funding to HRT, under the Funding Agreement, in the amount of $6,500,000 based on HRT's achievement of certain milestones set forth in the Funding Agreement;

WHEREAS, the Parties wish to amend and restate the Funding Agreement in its entirety;

WHEREAS, in addition to the funding provided under the Funding Agreement, PPLP has previously provided HRT funding to begin development of the Product including pursuant to prior written agreements between the Parties (the "Prior Agreements");

WHEREAS, this Agreement is intended to supersede all Prior Agreements between the Parties, other than the Letter Agreement dated November 9, 2017 (the "Confidentiality Agreement") and the Agreement dated as of July 29, 2019 (the "Right of Reference Agreement");

WHEREAS, PPLP is committed to addressing opioid use disorder and is seeking partners to support and accelerate impactful initiatives and scientific discoveries;

WHEREAS, HRT is interested in developing, marketing, seeking Regulatory Approval of, and distributing solely in the Territory a single dose, over-the-counter, naloxone intranasal spray device intended to treat opioid overdoses (the "Product");

WHEREAS, PPLP and HRT wish to enter into this Agreement pursuant to which PPLP will fund the continuation of HRT's development work in connection with the Product with the goal of having HRT seek Regulatory Approval of the Product and ultimately for HRT to be able to provide the approved Product to first responders, government agencies, not-for-profit entities, communities and individuals (collectively, "Contemplated Product Users"), subject to the terms and conditions set forth below.

NOW THEREFORE, HRT and PPLP, intending to be legally bound, hereby agree as follows:

ARTICLE I
DEFINITIONS

1.1 "Approval Order" means an order of the Bankruptcy Court, in form and substance reasonably acceptable to the Parties, approving PPLP's entry into this Agreement.

1.2 "Bankruptcy Court" means the United States Bankruptcy Court for the Southern District of New York having jurisdiction over the Chapter 11 Cases.

1.3 "Chapter 11 Cases" means the bankruptcy cases filed on September 15, 2019 by PPLP and certain of its affiliates under Chapter 11 of the United States Code in the Bankruptcy Court and jointly administered under Case No. 19-23649 (RDD).

1.4 "Claim" means, with respect to any Person, any claim, demand, action, proceeding, judgment, damage, loss, cost, expense, or liability whatever, incurred or suffered by or brought, made, or recovered against such Person (whether or not presently ascertained, immediate, future, or contingent) arising out of or relating to the sale or use of the Product by HRT or by any holder or user of the Product that in the chain of distribution came from or through HRT.

1.5 "Cost" means HRT's cost of goods sold for PPLP Funded Products (as defined in Section 2.3), on a fully absorbed basis, including general and administrative expenses, in accordance with United States generally accepted accounting principles, and any federal excise taxes and other federal, state and local taxes, as applicable.

1.6 "FDA" means the United States Food and Drug Administration, or any successor entity.

1.7 "GMP" means the then-current good manufacturing practices set forth in the quality system regulation 21 C. F. R. Part 820, governing the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use, as such practices may be updated from time to time.

1.8 "IND" means an Investigational New Drug Application as defined in the Federal Food, Drug and Cosmetic Act ("FD&C Act").

1.9 "Milestone Event" means any of the events set forth in Section 2.2 under the column "Milestone Event."

1.10 "Milestone Payment" means any of the payments set forth in Section 2.2 under the column "Milestone Payment."

1.11 "NDA" means a New Drug Application as defined in the FD&C Act.

1.12 "Original Effective Date" means the effective date of the Funding Agreement.

1.13 "Person" means any natural person, corporation (including any non-profit corporation), cooperative, company, foundation, general partnership, limited partnership, limited liability company, unlimited liability company, joint venture, estate, trust, association, organization, labor union, governmental body, custodian, nominee and any other individual or entity.

1.14 "Product Registration" means, in relation to the Product, an NDA that has been approved by the FDA, including any amendments or supplements.

1.15 "Regulatory Approval" means drug approval and all other approvals necessary for the distribution of Product in the Territory.

1.16 "Regulatory Authority" means any federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.17 "Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations, drug approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to develop, manufacture, market, sell or otherwise distribute Product in the Territory.

1.18 "RiVive" means the proposed name of 3.0 mg of the intranasal Product (as such name me be amended from time to time).

1.19 "Territory" means the United States of America, including its territories and possessions.

1.20 "Unit" means one package containing two RiVive intranasal naloxone devices.

ARTICLE II
EFFECTIVENESS; FINANCIAL ASSISTANCE

2.1 **Effectiveness**. This Agreement shall, upon entry of the Approval Order by the Bankruptcy Court and execution and delivery by the Parties, become effective and binding upon the Parties (such date, the "Amended and Restated Effective Date").

2.2 **Financial Assistance; Milestone Payments**.

(a) HRT will use commercially reasonable efforts to develop the Product and will use the funding provided by PPLP and referenced below only for (i) the development of the Product, (ii) other related activities, and (iii) general working capital, including legal and compliance costs and expenses.

(b) PPLP hereby agrees to provide funding to HRT in the form of Milestone Payments to encourage HRT's continued development of the Product in the Territory, payable after the achievement of certain Milestone Events. The Milestone Payments are described below:

Milestone Event and Primary Purpose	Milestone Payment	Expected Milestone Achievement/ Expected Payment Date
Clinical study successfully demonstrates that RiVive naloxone	$3,000,000	Completion date: January 31, 2022. Milestone achieved.

concentrations are as high as the FDA approved comparator product (Development, drug product stability, NDA preparation, device reliability and production equipment)		Payment Due Date: April 1, 2022
Acceptable drug product 24-month stability achieved to support targeted 24-month shelf life for commercial product (NDA preparation, pre-validation batch manufacture, sales & marketing preparations and on-going development work)	$3,000,000	Targeted completion date: August 31, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met
New Drug Application for RiVive filed with the FDA (Manufacturing site readiness, partial support of commercial batch components, sales and marketing support prior to 1st commercial shipment)	$5,000,000	Targeted completion date: October 28th, 2022 Payment Due Date: Within thirty (30) days after HRT delivers a written notice to PPLP that the applicable milestone has been met

The above referenced milestone achievement dates are expected dates only, are not intended to be deadlines and do not trigger any Milestone Payments (unless the Milestone Event has actually occurred). Each Milestone Payment is a one-time only payment based on the achievement of the Milestone Event; provided, that no Milestone Payment will be made unless the previously listed Milestone Event has been achieved. Promptly after HRT determines that it has achieved a Milestone Event, HRT shall provide notice thereof to PPLP in accordance with Section 9.2 hereof, which notice shall include sufficient detail of the achievement of such Milestone Event to enable PPLP to verify whether it agrees with HRT's determination. If, after receipt of the foregoing notice, PPLP agrees, reasonably and in good faith, that a Milestone Event has been achieved by HRT, PPLP shall pay the corresponding Milestone Payment to HRT within the time period set forth in the above chart after the date the Milestone Event was achieved or at such later time as HRT may request; provided, in no event will the Milestone Payment be due prior to the corresponding expected Payment Date set forth in the above chart. If PPLP does not agree that a Milestone Event has been achieved, the Parties will work in good faith to resolve any such dispute.

The aggregate amount of the Milestone Payments shall not exceed eleven million dollars ($11,000,000). Any amounts not funded in 2022 will be funded in the subsequent year; provided, that PPLP shall in no event be required to fund any amounts after March 31, 2023, regardless of whether a Milestone Event is achieved after such date.

Notwithstanding the foregoing, (i) if HRT licenses from a third party an FDA-approved product (i.e., with a Regulatory Approval) to serve as the Product, PPLP shall not make

the Milestone Payments referred to above, but the Parties will discuss in good faith any alternative funding that may be required by HRT to obtain approval for the Product (i.e., with a Regulatory Approval) to be distributed over-the-counter and (ii) if HRT receives any funding from any third party that is based on a new request or application made or submitted solely after the Original Effective Date to fund the development of the Product pre-commercialization, and such third party financing is received, such third party funding will reduce the amount of subsequent unpaid Milestone Payments by the amount of such third party funding (with the understanding that it will not reduce any other Milestone Payment hereunder and that HRT will have no obligation to return any Milestone Payments previously paid to HRT).

2.3 **Financial Assistance for HRT's Manufacture and Distribution of Product.**

As part of PPLP's public health initiatives, after FDA Regulatory Approval of HRT's NDA for the Product, PPLP may provide funds to HRT to enable HRT to manufacture Units of Product ("PPLP Funded Products") so that such Units can be donated free of charge or sold at Cost to Contemplated Product Users. The current market forecast for at Cost Units is depicted on Exhibit A attached hereto.

In the event PPLP does provide funding to HRT to enable HRT to manufacture PPLP Funded Products, at least two (2) months prior to each calendar quarter HRT and PPLP will agree upon a written annual forecast of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users as follows:

(i) a binding forecast for the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the upcoming calendar quarter, with projected delivery dates, sizes, strengths and ultimate destinations, as well as other relevant manufacturing and delivery information. PPLP shall fund one hundred percent (100%) of the Cost of such agreed upon forecast of PPLP Funded Products;

(ii) an estimate of the quantities of PPLP Funded Products to be manufactured and donated free of charge or sold at Cost to the Contemplated Product Users during the calendar quarter following the upcoming calendar quarter. PPLP shall fund at least fifty percent (50%) of the Cost of such forecast of PPLP Funded Products; and

(iii) a non-binding estimate of the forecast of PPLP Funded Products HRT intends to manufacture and which will be donated free of charge or sold at Cost to the Contemplated Product Users for the third and fourth calendar quarters of such forecast.

Each subsequent written forecast shall update the prior estimate and include an estimate of requirements for the next additional calendar quarter, so that estimates for a rolling one- (1-) year period are provided.

For avoidance of doubt, HRT shall not be obligated to produce and deliver any PPLP Funded Product to any Contemplated Product User unless PPLP has funded the applicable verifiable Cost related thereto, sufficient time in advance, as agreed upon by

the Parties, in accordance with the forecasts set forth above or otherwise (at an agreed upon rate reasonably calculated to allow HRT to diligently produce the Product). Any payments received by HRT in advance of the future donation or sale of PPLP Funded Products will be credited to the funding of the next forecasted quantities of PPLP Funded Products. Following the filing of an NDA for the Product, PPLP and HRT may further refine the forecasting provisions set forth above.

2.4 **Audit Rights.**

(a) Commencing as of the Original Effective Date and ending on the earlier of (i) termination or expiration of this Agreement, or (ii) the third anniversary of the latest delivered Milestone Payment, PPLP shall have the right to conduct audits of HRT's data and its books and records to reasonably determine whether Milestone Events have been achieved.

(b) Commencing as of the Original Effective Date, PPLP shall have the right to conduct audits of the books and records of HRT not more than once during each calendar year (i) until the date of Regulatory Approval of HRT's NDA for the Product, to determine that the funds provided by PPLP have been used in a manner consistent with Section 2.2 (a) and (ii) after FDA Regulatory Approval of HRT's NDA for the Product and until the termination of this Agreement, to verify HRT's Cost related to Units of Product.

(c) PPLP may exercise the audit rights described in (a) and (b) above by providing written notice to HRT and any such audit shall be conducted during normal business hours. HRT shall make available to PPLP such accounting and other books and records, reasonably requested by PPLP to exercise its rights hereunder.

2.5 **Reports**.

At least once during each month until the last Milestone Event has been achieved, HRT shall provide a written report to PPLP regarding its progress toward developing the Product and achieving the Milestone Events, including an update on the Expected Milestone Achievement Date for each such Milestone Event. Each report will account for HRT's expenditures of funding provided by PPLP allocated among the three categories set forth in Section 2.2(a). HRT shall also report on any funding that it received from third parties in connection with the Product, promptly after it becomes aware of such funding.

ARTICLE III
INTELLECTUAL PROPERTY

3.1 **Ownership of Data; Product Registrations**. HRT will be the sole owner of (a) all the data generated by HRT supporting development and registration of the Product, (b) the database of such data, (c) all Regulatory Approvals and Product Registrations in the

Territory, and (d) all Regulatory Materials, except as may be set forth in any other agreement between the Parties.

3.2 **IP Assignment**. HRT and its affiliates may assign, sell, license on an exclusive basis, or otherwise transfer any intellectual property related to the Product, only with the prior written consent of PPLP. Notwithstanding the foregoing, HRT and its affiliates may non-exclusively license the underlying intellectual property of the Product or any portion thereof in the ordinary course of business, in connection with the development, testing (including clinical trials), production or manufacture of the Product, upon notice to, but without the consent of, PPLP. Any purported assignment, sale or transfer of rights in or to any intellectual property in contravention of this Section 3.2 shall be null and void ab initio. The restrictions set forth in this Section 3.2 shall expire on December 31, 2031.

ARTICLE IV
REPRESENTATIONS, WARRANTIES AND COVENANTS

4.1 **Mutual Representations and Warranties**. Each Party hereby represents and warrants to the other Party as of the date hereof and as of the Original Effective Date and Amended and Restated Effective Date as follows:

A. **Authority**. It is validly existing and in good standing or active under the laws of the jurisdiction of incorporation or organization, has the power and authority to enter into this Agreement and has taken all necessary actions on its part required to authorize the execution and delivery of this Agreement. This Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement has been duly authorized by all necessary action on the part of such Party, its officers, directors, members and/or managers, as applicable.

B. **No Conflict**. The execution, delivery and performance of this Agreement by such Party does not, to such Party's knowledge, violate any material law or regulation or any order of any court, governmental body or administrative or other agency having authority over them. It is not currently a party to any material agreements, oral or written, that would cause it to be in breach of its obligations under this Agreement, and execution and delivery of this Agreement does not and will not conflict with, violate or breach any contractual obligations of such Party.

4.2 **HRT Representations, Warranties and Covenants**. HRT hereby further represents, warrants and covenants to PPLP that:

A. As of the Original Effective Date, HRT is and, during the term of this Agreement will continue to be, a nonstock corporation organized under the laws of the State

of Maryland. HRT shall not contemplate pecuniary gain or profit, incidental or otherwise, and no part of the net earnings of HRT shall inure to the benefit of or be distributed to any director or officer of HRT, or to any other private person, except that HRT shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of its charitable and/or public benefit purposes.

B. While receiving funding from PPLP under this Agreement, HRT will not participate in any lobbying activities that are prohibited by PPLP injunction(s), as delivered to HRT in writing from time to time. Advocacy by HRT before any Regulatory Authority regarding Regulatory Approval of the Product shall not be deemed to violate this Section 4.2(B).

C. HRT will develop the Product, manufacture PPLP Funded Products, and sell or donate PPLP Funded Products, in compliance with all applicable laws, including any applicable state transparency laws and applicable guidelines such as GMP (as and to the extent applicable to the PPLP Funded Products), then-current good clinical practice standards and procedures promulgated or endorsed by the FDA (as and to the extent applicable), then-current good laboratory practice standards promulgated or endorsed by the FDA and guidelines issued by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as and to the extent applicable).

D. HRT will use commercially reasonable efforts (taking into account the applicable global and local economic, health/pandemic and market conditions, as well as availability of funding) to obtain funding from third parties for the development of the Product and to supply funding for supply readiness and launch of the Product.

E. If HRT is no longer organized for charitable or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP, (x) HRT will provide written notice to PPLP that it is no longer so organized or no longer so qualifies, (y) HRT will repay to PPLP all amounts provided to it by PPLP under this Agreement no later than one (1) year after written request for such repayment is made by PPLP and (z) in PPLP's sole discretion but subject to HRT's receipt of any necessary governmental or regulatory approvals and compliance with applicable laws, PPLP will be entitled to forty percent (40%) of all of the equity interests in HRT. For clarity, denial of HRT's application for treatment as a tax exempt entity under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, by itself, will not mean that HRT no longer qualifies as an entity described above.

ARTICLE V
TERM AND TERMINATION

5.1 **Term**. This Agreement shall become effective on the Amended and Restated Effective Date and shall remain in effect until terminated pursuant to Sections 5.2, 5.3 or 5.4.

5.2 **Termination for Material Breach**. Either Party shall have the right to terminate this Agreement in the event that the other Party commits a material breach of this Agreement by giving written notice of such breach to the breaching Party. Termination shall be effective ninety (90) days after the giving of such notice unless the breaching Party has remedied the breach within such ninety (90) day period.

5.3 **Termination for Bankruptcy or Change of Status**. PPLP may terminate this Agreement upon notice to HRT if HRT becomes insolvent, makes any assignment for the benefit of its creditors, is placed in receivership, liquidation or bankruptcy or if it is no longer organized for charitable, or public benefit purposes or no longer otherwise qualifies as any of (i) a non-stock corporation, (ii) a benefit corporation, or (iii) another form of entity acceptable to PPLP. PPLP's right to terminate under this Section 5.3 is in addition to any of its rights under Section 4.2 E. of this Agreement.

5.4 **Termination by PPLP**. PPLP may terminate this Agreement, upon (x) fifteen (15) days' prior written notice if HRT has not achieved a Milestone Event set forth in Section 2.2 within one hundred eighty (180) days of the Targeted Completion Date set forth with respect to such Milestone Event or (y) sixty (60) days' prior written notice, if HRT has stopped using commercially reasonable efforts to develop Product in the Territory (during which sixty (60)-day period HRT may resume using such efforts and upon PPLP's reasonable satisfaction that such efforts have resumed such notice shall be withdrawn).

5.5 **Publicity Upon Termination**. If either Party terminates this Agreement for any reason, the Parties will agree upon the wording of any public announcement of such termination and, if the Parties are unable to reach such agreement, neither Party shall release any public announcement relating to such termination without the other Party's written consent. Following any termination of this Agreement, HRT will not make any public statements about this Agreement, the circumstances surrounding the termination or the relationship between the Parties without the prior written consent of PPLP, except for any such statements required pursuant to legal process. PPLP will give HRT prior written notice of any statement it proposes to make following such termination and, except for statements made pursuant to legal process, will take into consideration any comments HRT may have with respect to such statements. Notwithstanding the above, HRT may disclose the termination of this Agreement to any of its vendors or suppliers.

ARTICLE VI
INDEMNIFICATION

6.1 **Indemnification by HRT**. Except as otherwise specifically provided herein, HRT shall indemnify and hold harmless PPLP and its officers, directors, agents, employees, distributors, successors and assigns from and against all Claims, actions, losses, damages, costs, expenses or other liabilities in respect of any third party Claims arising out of (a) the use, development, marketing, seeking Regulatory Approval of or distribution of the Product by HRT, (b) breach of any of HRT's material obligations under this Agreement, including HRT's representations and warranties, or (c) the willful misconduct or grossly negligent acts of HRT, or the officers, directors, employees, or agents of HRT; provided that HRT shall have no liability or indemnification obligation under this Section 6.1 arising from liabilities to third parties principally caused by the acts or omissions of PPLP.

6.2 **Limitation of Liability**. EXCEPT WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY PROVISIONS SET FORTH IN ARTICLE VII, INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS PURSUANT TO SECTION 6.1, AND FAILURE TO COMPLY WITH THE ASSIGNMENT PREREQUISITES PURSUANT TO SECTION 3.2, NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANY OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

ARTICLE VII
CONFIDENTIALITY AND NONDISPARAGEMENT

7.1 **Confidentiality**. Except as otherwise agreed in writing between the Parties, the Parties will keep the terms of this Agreement confidential; provided, however, that either Party may disclose such terms (i) to the extent required by applicable law, (ii) to obtain Bankruptcy Court approval of the Approval Order or otherwise as may be reasonably required in connection with the confirmation or consummation of any plan of reorganization, (iii) as may be requested by any court appointed monitor of any PPLP injunction, or (iv) pursuant to any request for information from any other governmental entity or any compulsory legal process.

7.2 **Nondisparagement**. PPLP and HRT each agree that for a period of five (5) years from the Amended and Restated Effective Date, neither Party will disparage, portray in a negative or false light, or take any action that would lead to unfavorable publicity for the other Party or its employees or owners, whether such disparagement, portrayal, or action is made publicly or privately, in the form of opinion or otherwise and including, without limitation, in any and all interviews, verbal statements, written materials, and electronically-displayed materials; all of the above, only to the extent that such disparagement, portrayal, publicity or action relates to this Agreement, the Parties' on-going relationship, or PPLP's funding and support for HRT's development of the Product. Neither Party shall be deemed to be in breach of this Section 7.2 if the alleged disparagement, portrayal, publicity or action by such Party is truthful and is made in

connection with legally required testimony, pleading, investigation or any legal proceeding in front of a court, an arbitration panel or any governmental agency or entity.

ARTICLE VIII
COMMUNICATIONS, COOPERATION AND PRESENTATION OF RESEARCH

8.1 **Collaboration**. PPLP and HRT will collaborate on a public communications strategy related to HRT's development of the Product and PPLP's support thereof and will align on scheduled milestones for joint communications (e.g., press releases, social media, and statements), which may include up to four (4) opportunities per year.

8.2 **Presentation of Research**. If HRT intends to present research data related to the Product at a scientific forum or other public venue, it will notify PPLP not less than forty-five (45) days in advance of such event and HRT and PPLP will discuss whether and how PPLP's support of HRT and HRT's development will be referenced; provided that no such reference may be made without PPLP's prior written consent, which will not be unreasonably withheld. HRT and PPLP will also agree upon any press releases, social media releases or other announcements proposed to be made regarding such presentation.

8.3 **Websites and Social Media**. PPLP and HRT will continue to include information about funding and support provided by PPLP on both Parties' websites and through social media channels.

ARTICLE IX
MISCELLANEOUS PROVISIONS

9.1 **Assignment**. HRT shall not assign this Agreement without PPLP's prior written consent, which consent shall not be unreasonably withheld, provided however, that no such consent will be required in connection with the sale or transfer of all or substantially all of HRT's assets, provided that the successor to HRT shall be (i) a not for profit organization, (ii) a benefit corporation or (iii) another entity reasonably acceptable to PPLP, and shall have assumed, in a writing delivered to PPLP, all of the duties and obligations of HRT and shall agree to make all of the representations and warranties and observe all of the covenants of Section 4.2. PPLP may assign this Agreement or all of its rights and may delegate any or all of its obligations hereunder, provided that no such assignment shall be binding and valid until and unless the assignee shall have assumed, in a writing delivered to HRT, all of the duties and obligations of PPLP; provided that any assignment by PPLP in connection with the consummation of a plan of reorganization of PPLP shall be deemed to have satisfied the requirement of the delivery of such a writing.

9.2 **Notices**. Any notice or other communication which shall or may be given pursuant to this Agreement shall be in writing and shall be delivered by certified mail or by facsimile transmission confirmed by certified mail, addressed to the Parties' respective addresses as set forth below:

If to HRT: Harm Reduction Therapeutics, Inc.
4800 Montgomery Lane, Suite 400
Bethesda, MD 20814
Attn: President

With a copy to: K&L Gates LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, PA 15222-2613
Attn: Oded Green

If to PPLP: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: General Counsel

With a copy to: Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901
Attn: Chief Financial Officer

and

Arnold and Porter Kaye Scholer LLP
250 West 55th Street
New York, New York 10019-9710
Attn: Rory Greiss and Eric Rothman

Any Party may change its address by notice to the other Party.

9.3 **Further Assurances**. Each Party shall take all such steps, execute all such documents and do all such acts and things as may be reasonably required by the other Party to give effect to any of the transactions contemplated by this Agreement.

9.4 **Agency and Representation**. The legal relationship between the Parties shall not be construed such that any Party is deemed a partner or agent of the other Party, nor will it confer upon any Party the right or power to bind the other Party in any contract or to the performance of any obligations as to any third party. Each Party shall conduct its transactions and operations with the other as an independent contractor.

9.5 **Non-Waiver**. Neither the failure of any Party to enforce at any time any of the provisions of this Agreement nor the granting of any time or other indulgence shall be construed as a waiver of that provision or of the right of that Party thereafter to enforce that or any other provision.

9.6 **Severability**. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

9.7 **Costs**. Each Party shall bear its own costs arising out of the negotiation and preparation of this Agreement.

9.8 **Entire Agreement**. This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof, amends and restates in its entirety the Funding Agreement and supersedes all Prior Agreements, whether written or oral, other than the Confidentiality Agreement and Right of Reference Agreement, which will remain in full force and effect. This Agreement has no effect on the Agreement dated as of June 26, 2018, by and between HRT and Mundipharma International Corporation Limited (including its related Assignment and Bill of Sale and Assignment). Upon execution of this Agreement, other than the Confidentiality Agreement and Right of Reference Agreement, the Prior Agreements no longer remain in full force and effect.

9.9 **Amendment**. This Agreement may not be amended except by a further written agreement duly executed by authorized representatives of the Parties.

9.10 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to its choice of law and conflicts of law provisions.

9.11 **Counterparts**. This Agreement may be executed in two or more counterparts (including by facsimile or other electronic transmission), each of which shall be deemed an original, but all of which together shall constitute a single agreement.

9.12 **Third-Party Beneficiaries**. Except as specifically provided herein, this Agreement is not intended to confer upon any non-party any rights or remedies hereunder.

9.13 **Survival**. The provisions of Section 3.1 and Articles VI, VII and IX shall survive the termination of this Agreement.

9.14 **Force Majeure**. Each Party will be excused for delays in performing or from its failure to perform hereunder to the extent that the delays or failures result from causes beyond the reasonable control of such Party; provided that, in order to be excused from the delay or failure to perform, such Party much act diligently to remedy the cause of the delay or failure.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed by their duly authorized representatives as of the date first written above.

HARM REDUCTION THERAPEUTICS, INC.

_____

BY: Michael Hufford, Ph.D.
TITLE: CHIEF EXECUTIVE OFFICER

PURDUE PHARMA L.P.

By: PURDUE PHARMA INC., ITS GENERAL PARTNER

_____

BY:
TITLE:

Exhibit A

Market Forecast of OTC Naloxone at Cost Units										
2022	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**Cumulative**
0	-	469,861	1,107,130	1,660,872	1,857,501	2,018,270	2,077,035	2,137,686	2,200,288	13,528,642